

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.                        | FILING DATE                         | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------------------------------|------------------------|---------------------|------------------|
| 10/825,742                             | 04/16/2004                          | Robert R. Alfano       | 5250-9              | 8494             |
|  | 7590 01/04/200<br>TANI, LIEBERMAN & | EXAMINER               |                     |                  |
| Suite 1210                             |                                     | FERNANDEZ, KATHERINE L |                     |                  |
| 551 Fifth Avenue<br>New York, NY 10176 |                                     |                        | ART UNIT            | PAPER NUMBER     |
|  |                                     |                        | 3768                |                  |
|  | •                                   |                        | <u>.</u>            | •                |
| SHORTENED STATUTOR                     | Y PERIOD OF RESPONSE                | MAIL DATE              | DELIVERY MODE       |                  |
| 3 MONTHS                               |                                     | 01/04/2007             | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.   | Applicant(s)      |  |  |  |
|--|---|-------------------|--|--|--|
| •  | 10/825,742  | ALFANO ET AL.     |  |  |  |
| Office Action Summary  | Examiner  | Art Unit          |  |  |  |
|  | Katherine L. Fernandez  | 3768              |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                   |  |  |  |
| Status   |   |                   |  |  |  |
| 1) Responsive to communication(s) filed on 16 Ag   | <u>oril 2004</u> .  |                   |  |  |  |
| 2a)  This action is <b>FINAL</b> . 2b)  This   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |                   |  |  |  |
| 3) Since this application is in condition for allowan  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                   |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                   |  |  |  |
| Disposition of Claims  |   |                   |  |  |  |
| 4) Claim(s) is/are pending in the application.   |   |                   |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |                   |  |  |  |
| 5) Claim(s) is/are allowed.  |   |                   |  |  |  |
| 6)⊠ Claim(s) <u>1-25</u> is/are rejected.  |   |                   |  |  |  |
| 7) Claim(s) is/are objected to.  |   |                   |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  |   |                   |  |  |  |
| Application Papers   |   |                   |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                   |  |  |  |
| 10)⊠ The drawing(s) filed on <u>16 April 2004</u> is/are: a) accepted or b)⊠ objected to by the Examiner.  |   |                   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                   |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                   |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                   |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                   |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |   |                   |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |                   |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |                   |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |                   |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |                   |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |                   |  |  |  |
|  |   |                   |  |  |  |
|  |   |                   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)   |   |                   |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>   | Paper No(s)/Mail Da   | te                |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date   | 5) Notice of Informal Page 1975   | atent Application |  |  |  |

Art Unit: 3768

### **Priority**

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(3) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

### **Drawings**

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: element 217 (Fig. 3) and element 221 (Fig. 3). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Specification

3. The disclosure is objected to because of the following informalities:

Figures 13-15 are not included in the "Brief Description of the Drawings" section of the disclosure.

Art Unit: 3768

On page 14, line 7, there is a grammatical error. The sentence should be rewritten as "The monitoring of water concentration may advantageously be exploited to determine the state of the tissue, thus aiding in the diagnosis of cancerous, precancerous, and normal tissues."

Appropriate correction is required.

## Claim Objections

4. Claims 12, 23 and 25 are objected to because of the following informalities:

Regarding claim 12, in the first line, the claim refers to the spectral optical imaging system of claim 9. However, claim 9 refers to a method. It is assumed that this is a typo, and claim 11 is being referenced to.

Regarding claim 23, in the sixth line, "on" is a typo and should be changed to "one". Further, in the tenth line, "on" is a typo and should be changed to "one".

Regarding claim 25, in the first line, the claim refers to the spectral optical imaging system of claim 10. However, claim 10 refers to a method. It is assumed that this is a typo, and claim 11 is being referenced to. Further, assuming that the applicant wanted to refer to claim 11, claim 25 is a repeat of claim 12 of the instant application.

Appropriate correction is required.

# Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 3768

regards as the invention. The claim is considered as indefinite since the parent claim 12 specifies a range of 400 to 1800 nm for the low or neglible water absorption wavelength, and the instant claim specifies wavelengths outside of this range.

### Double Patenting

- 7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).
- 8. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.
- 9. Claims 1-25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application No. 10/926556. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

# Claim Rejections - 35 USC § 102

- 10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
  - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 11. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Alfano et al. (U.S. Patent No. 6,665,557). The applied reference has a common inventor with

under 37 CFR 1.131.

the instant application. Based upon the earlier effective U.S. filling date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing

Page 5

Regarding claim 1, Alfano et al. disclose a method for imaging objects in turbid media, such as detecting a tumor within an organ (column 3, lines 24-35). Claim 41 of the reference patent discloses a method of imaging an object in a turbid medium by illuminating the turbid medium with two wavelengths (column 25, lines 56-67 through column 26, lines 1-28). One wavelength is within the 940-1010 nm range or in the 1400-1500 nm range (column 26, lines 23-28). Alfano et al. teach that imaging with light in the above specified ranges can be used to map the water distribution in the breast (column 4, lines 44-52). The second wavelength is outside these ranges (column 26, lines 44-52). The difference image highlights the water distribution and thus lesions may be detected based on the changes in water content of the tissue (column 26, lines 44-52).

Regarding claim 2, as discussed above, Alfano et al. teach a method for imaging an object in a turbid medium, wherein one of the two wavelengths is in the 940-1010 nm range or in the 1400-1500 nm range, which would result in a water distribution map (column 4, lines 44-52). Alfano et al. teach that two of the claimed wavelengths fall within the range 940-1010 nm or within the range 1400-1500 nm (U.S. Patent No.

6,666,557). Alfano et al. further teach a second wavelength outside of the 940-1010 nm range and the 1400-1500 nm range (column 26, lines 23-28). The applicants claim that they perform optical imaging at one or more wavelengths of low or negligible water absorption in the range of 400 nm to 6000 nm, which overlaps with the range specified for the second wavelength disclosed by Alfano et al (column 26, lines 23-28). As discussed above, a difference image highlights the water distribution and thus lesions may be detected.

Regarding claims 3-4, as discussed above, Alfano et al. teach a range that is outside the 940-1010 nm and 1400-1500 nm range for the second wavelength (column 26. lines 23-28). Most of the specified wavelengths of lower or neglible water absorption claimed by the applicant fall within the range specified by Alfano et al (column 26, lines 23-28).

Regarding claims 5-6, Alfano et al. disclose in claim 41 of their patent that a difference image highlights the water distribution and enables the detection of lesions that involve changes in water content of the tissue (column 26, lines 23-28).

Regarding claims 7-8, Alfano et al. teach that their invention may be used in the detection of tumors and other abnormalities in human body parts, such as the prostrate (column 3, lines 30-35). Some of the specified wavelengths claimed by the applicant for deep prostate cancer detection and for surface and subsurface prostate cancer detection fall within the 940-1010 nm and 1400-1500 nm range disclosed in claim 1 of the patent.

Art Unit: 3768

Regarding claim 9-10, Alfano et al. teach that their invention may be used in the detection of tumors and other abnormalities in human body parts, including the breast, cervix, and skin, as well as other organs (column 3, lines 30-35).

### Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 11-13, 15-16, 19, 21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312).

Regarding claim 11, Alfano et al. (U.S. Patent no. 6,665,557) disclose an apparatus for imaging objects in a turbid medium (column 3, lines 24-25). Their apparatus includes a laser light, which serves as the source of illumination, and a polarization gate that consists of a first polarizer before the sample cell and a second polarizer before the camera (column 8, lines 10-40). Alfano et al. (U.S. Patent No. 6,665,557) further disclose that the light detector used in their apparatus can be a CCD camera (column 13, lines 30-36). As discussed previously, their method includes using two wavelengths, where the first wavelength is in the range of 940-1010 nm or in the range of 1400-1500 nm, and the second wavelength is outside of these ranges. However, Alfano et al. (U.S. Patent No. 6,665,557) do not disclose that their apparatus includes first and second wideband filters. Further, they do not specifically disclose that the wideband filters include a selection mechanism enabling selection of at least one water absorption wavelength (including at least one of 980 nm, 1195 nm, 1456 nm, 1944 nm, 2700-3600 nm, and 4720 nm) and at least one reference wavelength (including at least one infrared wavelength that provides negligible water absorption). Alfano et al. (U.S. Patent No. 6,240,312) discloses a device that is designed to detect and/or treat diseased biological materials, such as tissue, inside a patient's body (column 2, lines 8-11). Their device includes a spectroscopic imaging system that uses wideband filters that may be rotated on a MEMS rotation wheels to select different

wavelengths to measure light intensities for processing (column 6, lines 22-34). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the apparatus by Alfano et al. (U.S. Patent No. 6,665,557) to include first and second wideband filters with a selection mechanism enabling selection of at least one water absorption wavelength and at least one reference wavelength. The motivation for doing so would have been to be able to select different wavelengths, as taught by Alfano et al. (U.S. Patent No. 6,240,312, column 6, lines 22-34).

Regarding claims 12 and 25, Alfano et al. (U.S. Patent No. 6,665,557) disclose a method that uses the apparatus discussed above to detect cancerous tissue (column 3, lines 30-35). The method involves illuminating the tissue with two wavelengths (column 25, lines 56-67 and column 26, lines 1-28). One wavelength is in the 940-1010 nm range or in the 1400-1500 nm range, which maps water distribution (column 4, lines 35-52). The other wavelength is outside of these two ranges (column 26, lines 23-28). A difference image is created and highlights the water distribution, enabling the detection of lesions that involve changes in the water content of the tissue (column 26, lines 23-28). The apparatus, as discussed above, can include a CCD camera to detect the light. However, Alfano et al. (U.S. Patent No. 6,665,557) do not disclose the use of wideband filters that are adjusted to pass electromagnetic energy at least one of 980 nm, 1195 nm, 1456 nm, 1944 nm, 2880 nm to 3360 nm, and 4720 nm to generate the water absorption image. Further, they do not disclose the use of the wideband filters to pass electromagnetic energy at one or more low or negligible water absorption wavelengths in the range of 400 nm to 1800 nm to generate the reference image. As discussed

above, Alfano et al. (U.S. Patent No. 6,240,312) disclose the use of wideband filters in their invention. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the method of Alfano et al. (U.S. Patent No. 6,665,557) to use wideband filters that are adjusted to pass electromagnetic energy at the specified wavelengths to generate the images. The motivation for doing so would have been to provide a mechanism that would allow the selection of the different wavelengths, as taught by Alfano et al. (U.S. Patent No. 6,240,312, column 6, lines 22-34).

Regarding claim 13, Alfano et al. (U.S. Patent No. 6,665,557) disclose that the second wavelength is outside the 940-1010 nm range and outside of the 1400-1500 range (column 26, lines 23-28).

Regarding claim 15, Alfano et al. (U.S. Patent No. 6,665,557) disclose that their invention may be used in the detection of tumors and other abnormalities in human body parts, such as the prostrate (column 3, lines 30-35). Some of the specified wavelengths claimed by the applicant for deep prostate cancer detection and for surface and subsurface prostate cancer detection fall within the 940-1010 nm and 1400-1500 nm range disclosed in claim 1 of the patent.

Regarding claim 16, Alfano et al. (U.S. Patent No. 6,665,557) disclose that their invention may be used in the detection of tumors and other abnormalities in human body parts, including the breast, cervix, and skin, as well as other organs (column 3, lines 30-35).

Regarding claim 19, Alfano et al. (U.S. Patent No. 6,665,557) disclose the use of a CCD camera for detecting light (column 13, lines 31-36). The wavelengths specified

Application/Control Number: 10/825,742

Art Unit: 3768

in their method are within the near-infrared region, which lies between the red visible to mid-IR wavelength region (column 26, lines 23-28).

Regarding claim 21, Alfano et al. (U.S. Patent No. 6,665,557) disclose using a polarization gate in their imaging system (column 8, lines 35-40). The polarization axis of the second polarizer before the camera was made adjustable to enable the parallel and perpendicular components of the light to be measured (column 8, lines 35-40).

16. Claims 14,17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (U.S. Patent No. 6,665,557) and Alfano et al. (U.S. Patent No. 6,240,312) as applied to claims 11-12 above, and further in view of Alfano et al. (U.S. Patent No. 5,847,394).

Regarding claim 14, Alfano et al. (U.S. Patent No. 6,665,557) disclose creating a difference image that highlights the water distribution (column 26, lines 23-28). However, Alfano et al. (U.S. Patent No. 6,665,557) do not disclose that the imaging system includes a graphical processing mechanism for generating the difference image from the water absorption image and the reference image on a pixel by pixel basis. Alfano et al. (U.S. Patent No. 5,847,394) disclose a method for imaging an object located in or behind a turbid medium based on the polarization of light (column 6, lines 52-65). Their system includes a computer (23) for analyzing the information detected by the detector (19), as well as a monitor (25) for displaying the image of the tissue sample. See Figure 7. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the invention of Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312) to include a computer

capable of graphical processing to generate the difference image on a pixel-by-pixel basis. The motivation for doing so would have been to be able to analyze the information detected by the detector as taught by Alfano et al. (U.S. Patent No. 5,847,394) (column 13, lines 42-47).

Regarding claim 17, Alfano et al. (U.S. Patent No. 6,665,557) disclose creating a difference image that highlights the water distribution, thus enabling the detection of lesions that involve changes in the water content of the tissue (column 26, lines 23-28). However, they do not disclose that their invention includes a graphical processing mechanism that subtracts the water absorption images from the reference image, nor that it is programmed to perform the subtraction. Alfano et al. (U.S. Patent No. 5,847,394) disclose that their imaging technique involves recording two image polarization components and obtaining the final image of the object by subtracting the perpendicular image component from the parallel image component (column 11, lines 17-22). The difference of the two polarization image components can be replaced by any image operation, including the ratio of the two components (column 12, lines 57-61). As discussed above, their invention includes a computer and monitor in their imaging system for analyzing the information detected by the detector regarding the parallel and perpendicular components and displaying the resulting image (column 13, lines 42-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the invention of Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312) to include a computer capable of graphical processing and is programmed to perform the subtracting of the

water absorption image and the reference image. The motivation for doing so would have been to be able to efficiently analyze the information detected by the detector as taught by Alfano et al. (U.S. Patent No. 5,847,394) (column 13, lines 42-47).

Regarding claim 20, Alfano et al. (U.S. Patent No. 6,665,557) in view of (U.S. Patent No. (6,240,312) do not disclose a computerized imaging system coupled to the CCD camera, wherein the computerized imaging system includes a processing mechanism for executing data collection software and for posting images to a display screen. Alfano et al. (U.S. Patent No. 5,847,394) disclose that their imaging system includes a computer and a monitor in their imaging system for analyzing the information detected by the detector and for displaying the resulting image (column 13, lines 42-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the invention of Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312) to couple a computerized imaging system to the CCD camera that includes a processing mechanism for executing data collection software and post images to a display screen. The motivation for doing so would have been to be able to efficiently analyze the information detected by the detector as taught by Alfano et al. (U.S. Patent No. 5,847,394) (column 13, lines 42-47)

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312) as applied to claim 12 above, and further in view of Alfano et al. (U.S. Patent No. 5,799,656).

Application/Control Number: 10/825,742

Art Unit: 3768

Alfano et al. (U.S. Patent No. 6,240,312) disclose that the light source for their invention is preferably one or more light-emitting diodes (LEDs). However, Alfano et al. (U.S. Patent No. 6,665,557) do not disclose that their system further comprises a coupling mechanism for coupling the source to a tissue through an optical subsystem including at least one of a filter, a lens, a mirror, a beam splitter, a polarizer, optical fiber, a CCD detector, and a CMOS detector. Alfano et al. (U.S. Patent No. 5,799,656) disclose a technique for cancer-screening breast tissue for calcifications using optical imaging (column 6, lines 11-31). Their system includes a beam splitter and mirrors, as well as lenses and a polarizer (column 6, lines 38-62). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the invention of Alfano et al. (U.S. Patent No. 6,665,557) in view of Alfano et al. (U.S. Patent No. 6,240,312) to include a coupling mechanism for coupling the source to a tissue through an optical subsystem including at least one of a filter, a lens, a mirror, a beam splitter, a polarizer, optical fiber, a CCD detector, and a CMOS detector. The motivation for doing so would have been to reflect and focus the light, as taught by Alfano et al. (U.S. Patent No 5,799,656) (column 6, lines 38-48).

18. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (U.S. Patent No. 6,665,557) in view of Kiricuta et al ("Tissue Water Content and Nuclear Magnetic Resonance in Normal and Tumor Tissues", May 1975).

Regarding claims 22 and 23, as discussed above, Alfano et al. disclose a method for detecting a tumor within an organ (column 3, lines 24-35). The method includes illuminating the tissue with two wavelengths (column 25, lines 56-68 through column 26,

lines 1-28). One wavelength is selected in the water absorption range (940-1010 nm range or in the 1400-1500 nm range) to create a water distribution image and the other wavelength is selected outside of this range, thus creating a reference image (column 26, lines 23-28 and column 4, lines 44-52). A difference image is created which highlights the water distribution, which enables the detection of lesions that involve changes in water content of the tissue (column 26, lines 23-28). However, Alfano et al. do not disclose that if a region has lower water content than a second region of tissue. the first region of tissue is diagnosed as cancerous or precancerous in an early stage of cancer, nor do they disclose that if the first region of tissue has a higher water content than a second region of tissue, then the first region of tissue is diagnosed as cancerous or precancerous region in a later stage of cancer. Kiricuta et al. disclose the use of pulsed photon nuclear magnetic resonance to differentiate between normal and malignant tissues. They observed differences between the relaxation times of the normal and malignant tissue, and concluded that the main cause for this difference was the higher water content in malignant tissue than in normal tissue (pg. 1166). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the method of Alfano et al. to include the step of diagnosing regions of tissue as cancerous or precancerous and identifying early and later stages of cancer based on a comparison of the water content. The motivation for doing so would have been that it has been shown that malignant tissue has higher water content than normal tissue, as taught by Kiricuta et al.

Art Unit: 3768

Regarding claim 24, Alfano et al. disclose that their method may be used to detect tumors in human body parts, including the breast (column 3, lines 30-35).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ELENI MANTIS MERCADER SUPERVISORY PATENT EXAMINER

lembarte